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C. R. Bard, Inc. Bard Peripheral Vascular, Inc. 1415 W. 3rd St PO Box 1740 Tempe, AZ 85280-1740				
EXAMINER				
WOZNICKI, JACQUELINE				
ART UNIT		PAPER NUMBER		
3774				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary**Application No.**

10/585,722

Applicant(s)

LAITENBERGER ET AL.

Examiner

JACQUELINE WOZNICKI

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3, 6, 7, 11, 15-24, 26 and 27 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-3, 6-7, 11, 15-24, 26-27 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-889)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s) Mail Date ____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/25/11 have been fully considered but they are not persuasive.

On page 6, regarding claim 1, Applicant argues that Gray fails to disclose a spiral or helically wound loops that are wrapped around an axis as is claimed. Applicant argues that the spiral indication that is "arbitrarily drawn" by the Examiner and that a mesh stent can not fairly be interpreted as the claimed closed loops being helically wound around the longitudinal axis.

Examiner respectfully disagrees and notes that the spiral/helically wound loops are not arbitrarily drawn in by Examiner, but that the loops (which are understood to be each loop (Figure 3, items 132, 134, 136, 138), arranged within a mesh structure, which is clearly shown to be a diagonal mesh. Examiner notes further that a diagonally oriented mesh, which is curved into a tubular shape (such as is shown in Figure 10), *does* result in its loops that make up the mesh being helically wound around the longitudinal axis that is created within the tubular shape when the mesh is curved.

On page 7, regarding claim 1, Applicant further argues that the Examiner's annotation has removed the junctions (222) that clearly lie between the connected mesh strands, and that the junctions are positioned at each strand crossing of the mesh structure, and so fails to describe or show the claimed arrangement of loops.

Examiner respectfully disagrees, noting that Gray teaches the conductive strands (221) forming just about any pattern ([0099]), and that Figure 10 shows the pattern of

the strands indicating a helically wound configuration. Examiner is not sure how Applicant's arguments with respect to the conductors realizing immunity from EMF interference or insult supports their arguments with respect to the arrangement of closed loops, and so does not consider this persuasive.

On page 7, with respect to Gray in view of Bucker, Applicant argues that Bucker is presumably cited under 35 USC 102(2) due to the unavailability of the Bucker, US application under 35 USC 102(e). Examiner respectfully disagrees and, referring to the Non-Final rejection, notes that Bucker is applied under 35 USC **103(a)**.

On page 7, regarding claims 6-7 and 9-10, Applicant argues that Bucker fails to teach strut loops wrapping around an axis with an integral number of whole turns. Applicant argues that Bucker cannot show loops *wrapping* around an axis with an integral number of *whole turns* because the loops stop short of 360 degrees. Further, Applicant argues that Bucker does not teach closed circuits.

Examiner respectfully disagrees and notes that the figures 4a-4g are separate embodiments of endoprostheses, and that while figures 4b and 4c appear to have loops that stop SHORT of 360 degrees, the *cited* embodiment (Figure 4a), shows loops that extend in whole turns (360 degrees) as is claimed, further noting that *Gray* discloses closed circuits, and that Bucker was not relied upon for electrically conductive closed circuits.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "equal area counterpart lobe" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

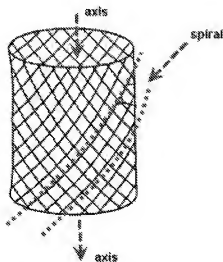
Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 states that the lobes are circumferentially separated from an equal area counterpart lobe by 180 degrees. However, the claim from which it depends claims that the stent comprises loops, loops comprising struts, and the loops being formed from strut loop portions. However, the specification does not provide support for the loops portions having a plurality of lobes that are each separated from a counterpart lobe by 180 degrees. It appears that this is either new matter, or an indefinitely worded claim. For example, from this claim it is not clear whether the strut loop portions have a plurality of lobes *each*, whether the equal area counterpart lobe is *part of* the plurality of lobes, or another explanation. Further, for this claim, it appears the drawings and/or specification fails to support this claim (for example, the drawings do not show the lobes each separated from a counterpart lobe *circumferentially* by 180 degrees, while they would support the lobes being separated from counterpart lobes that have been twisted 180 degrees). For the purposes of Examination, Examiner is interpreting this as a 112 2nd paragraph claim issue as opposed to a 112 1st paragraph and/or drawing issue.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6-7, 11, and 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (US 20050049683 A1), hereinafter known as Gray in view of Bucker (WO 03015662 A1; US 20040249440 A1) is being used as a translation thereof).



Annotated Figure 10

Regarding **claims 1 and 6-7**, Gray discloses an implant comprising:

a tubular metal stent (Figure 3 (tubular); Abstract (metal); [0018] (stent))
defining a lumen centered on a central longitudinal axis (Annotated Figure 10; "axis"), **the stent being radially expansible from a radially compact delivery configuration to a radially larger deployed configuration** ([0114]),
a plurality of electrically-conductive closed loops comprising struts forming an apertured wall of the stent (Figure 3, items 132, 134, 136, 138 (loops) and [0095]; the curved segment loops form the meshed wall of the stent. The struts are the "strands", Figure 10 item 221.),

said loops being helically wound around the longitudinal axis
(Annotated Figure 10),

each of said loops being formed from strut loop portions (Figure 1, items 102, 104) **providing electrically-conductive current pathways within which eddy currents are liable to be induced when subjected to a time-dependent external magnetic field** (Figure 1, item 110, 112), **each of said loops including a first current pathway and a second current pathway** ([0076]) **wherein said first current pathway and said second current pathway are arranged such that, regardless of the direction of said external magnetic field, the direction of the eddy current that would be induced by said field in said second current pathway is the reverse of the direction of the eddy current that would simultaneously be induced by said field in said first current pathway, thereby to prevent flow of eddy currents in each of said loops, thereby mitigating a Faraday Cage effect and rendering the lumen visible to MRI** (Abstract)

but fails to disclose the loops wrapping with an integral whole number of turns, the number of turns being at least three, and the pitch of the spiral being constant.

However, regarding **claims 1 and 6-7**, Bucker teaches strut loops wrapping around an axis with an integral number of whole turns (Figure 4a), and at least three turns (Figure 4a shows four turns), and the pitch of the spiral being constant (Figure 4A). Gray and Bucker are involved in the same field of

endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Gray by having at least three turns as is taught by Buckner in order to have a stent that is long enough to cover a diseased area and prevent restenosis an entirety of a problem area. Although dependant on the implantation site and the amount of diseased vasculature, the number of turns would be able to be optimized to correspond to the length of the stent needed. Further, it would have been obvious to have the pitch of the spiral path be constant in order to simplify the manufacturing process. By not changing the pitch of the spiral, the process of manufacture will take less time and be simpler, since calculations and modifications would not have to be made to change the pitch.

Regarding **claim 2**, Gray further discloses the strut loop portion formed as a plurality of lobes (Figure 2, items 126, 128), each lobe being circumferentially separated from an equal area counterpart lobe by 180 degrees (Figures 3-6, 10) Figure 10 shows loop portions being formed the entire circumference of the stent, including 180 degrees from every other lobe. Examiner notes that although the drawings are not interpreted as being to scale, Examiner understands the conductive material of the mesh/loops is *much* smaller than the open space between the loops (which are the lobes), and so inherently, each lobe is circumferentially separated from a counterpart lobe by 180 degrees, since the mesh material can not possibly occupy the entirety of the space of a lobe).

Further, Examiner understands that the lobes and counterlobes of the loops have the same area, since they are all purposely drawn to the same scale (Figure 2, items 126, 128). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gray by having the lobes and counterpart lobes to have equal area in order to make the manufacture of the stent simpler. Creating a mesh of loops, lobes, and counterlobes that are equal area is easier than to create a mesh of loops, lobes, and counterlobes that have different areas.

Regarding **claim 3**, Gray discloses the implant of claim 2, further comprising an electrically-insulating joint between said two loop portions at the cross-over point ([0077]).

Regarding **claim 11**, Gray further discloses wherein loop portions correspond to struts that are joined end-to-end to each other (Figure 5) and can deploy in use to form a zig zag pattern ([0085]; zig zag).

Regarding **claims 26-27**, Gray further discloses the implant being made of Nitinol or stainless steel (Abstract).

Claims 15-16, 18-19, 21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Bucker as applied above to claim 1 and further in view of Blank (WO 03/075797 A2).

Regarding **claims 15-16, 18-19, 21, and 23-24**, the modified Gray discloses the invention substantially as claimed, but fails to disclose the

electrically insulating links being mechanical couplings movable to each other, with a hook and an eye, a layer of ceramic or adhesive bonding material, the couplings being interlocking fingers, mechanically engaging surfaces, having an overlying restraining strap, a molded connector piece, or a thinned portion, and having first and second cooperating link portions.

However, regarding **claims 15-16, 18-19, 21, and 23-24**, Blank teaches a stent visible in MRI with electrically insulating mechanical couplings (Figure 5), with a first cooperating link portion (Figure 5, item 32) and a second cooperating link portion (Figure 5, item 34),

wherein the cooperating portions can move relative to each other ([0072]), wherein including a layer of bonding material between the cooperating link portions ([0071]; the pin (Figure 4, item 26) comprises the "bonding material" because it is located between the cooperating link portions, bonds the two portions together, and has at least one layer of a material)

wherein the bonding material is ceramic ([0071]; the pin may be ceramic), wherein the mechanical coupling comprises interlocking fingers (Figure 4, item 22 and 24),

wherein each link includes a molded connector piece (Figure 4, [0071]; a pin is a molded connector piece).

wherein each link includes a portion that is locally thinned with respect to the thickness of the wall implant (Figure 5; portions 32 and 34 are at least about half the thickness of the wall implant).

Gray, Bucker, and Blank are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Gray by using the mechanical couplings as taught by Blank in order to have a variety of connectors for the stent struts of Gray. This way, the degree of flexibility of the stent and mobility of struts relative to one another can be controlled, and a more flexible stent will result. This will allow the stent to be implanted in a variety of vessels, for example, very tortuous vessels that require a stent that is flexible.

Claims 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Bucker as applied above to claim 1 and further in view of Pacetti (US 6712844 B2)

Regarding **claims 15, 18, and 20**, the modified Gray discloses the invention substantially as claimed with an electrically insulating material connecting link portions (Figure 11, item 234), but fails to disclose a layer of adhesive bonding material or ceramic bonding material between the first and second cooperating link portions. However, Pacetti discloses mechanical coupling linkage (Figure 8, Column 8 lines 7-9) with a layer of bonding material between first and second cooperating link portions in the form of an adhesive (Column 7, lines 2-13; adhesive), or a layer of ceramic (Column 7, lines 38-39).

Gray, Bucker, and Pacetti are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at

the time the invention was made to modify the stent of the modified Gray by using the mechanical connections as taught by Pacetti because they are recognized alternatives in the art as strut connectors. Using the specific adhesive or ceramic bonding materials as taught by Pacetti would further be obvious to ensure complete biocompatibility and the ability to hold the portions together even under body conditions, ensuring the stent remains together in place as long as needed without coming apart.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Bucker and Blank, as applied above to claim 16 in view of Raulerson (US 5599311 A).

Regarding **claim 17**, the modified Gray discloses invention substantially as claimed in claim 16, but fails to disclose a hook and eye portion holding mechanical linkages together.

However, regarding **claim 17**, Raulerson teaches two cooperating portions of a stent being held together by a hook and eye (Column 7, lines 35-41; Velcro). Gray, Bucker, Blank, and Raulerson are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of the modified Gray by using a hook-and-eye closure for connecting links as is taught by Raulerson in order to increase the flexibility of the stent at every connection point. Velcro (hook-and-eye connections) allow movement relative to each side,

and so the flexibility of the stent will increase, allowing the stent to be implanted in a variety of tortuous vessel with ease.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Buckner and in view of Blank as applied above to claim 15, and further in view of Lenker et al. (US 6176875 B1), hereinafter known as Lenker.

Regarding **claim 22**, the modified Gray discloses the invention substantially as claimed in claim 15, but fails to disclose mechanically engaging surfaces in combination with at least one restraining strap. However, regarding **claim 22**, Blank teaches mechanical coupling comprises mechanically-engaging surfaces (Figure 5) and Lenker teaches at least one restraining strap overlying strut link portions (Figure 5c, item 102).

Gray, Buckner, Blank, and Lenker are involved in the same field of endeavor, namely stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of the modified Gray in view of the mechanically engaging surfaces as taught by Blank in order to be able to control the degree of flexibility of the stent. By having the connections of Blank, a more flexible stent will result, allowing the stent to be implanted in a variety of vessels, for example, very tortuous vessels that require a stent that is flexible.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the restraining strap as taught by Lenker in order to restrain the stent until ready for expansion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE WOZNICKI whose telephone number is (571)270-5603. The examiner can normally be reached on M-R, 10 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, David Isabella, at (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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12/31/11